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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,972	12/15/2003	Andrea Pereira	07917-198001 / UMMC 03-69	5625
26161	7590	09/07/2006	EXAMINER MONSHIPOURI, MARYAM	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/735,972	Applicant(s) PEREIRA ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 9-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>filed 6/20/2006 (2 IDS papers)</u> | 6) <input type="checkbox"/> Other: ____ |

Applicant's response to restriction requirement filed 6/19/2006 is acknowledged. Applicant elected Group I(b) invention with traverse. In traversal of restriction applicant provides the following arguments **(1)** that Groups I(a) and I(d) are improper because the instant invention is directed to a method of use of KIF18 polypeptides and not to the method of use of genes encoding KIF18A. **(2)** That there is no burden of searching on the examiner if Groups I(b) and I(c) are examined together and therefore said inventions should be rejoined.

These arguments were fully considered but were found **unpersuasive**. In response to applicant's **first** argument the examiner accepts applicant's argument and maintains that the only reason said restriction was held was to obtain a written clarification that the instant elected invention is in fact directed only to a method of use of polypeptides and not their encoding genes. Restriction between Groups I(a)-1(b) and 1(c) –1(d) is hereby withdrawn.

With respect to applicant's **second** argument the examiner respectfully disagrees that rejoinder of Groups I(b) and I(c) does not impose an undue burden of searching on the examiner. Applicant is well aware that modulators which bind KIF18A have a totally different structure and function than those that modulate the active site of said polypeptide Therefore, the steps and end-points in each invention is different and even though there may be some overlap between the search requirements of said invention said searches are **not coextensive**. For said reasons rejoinder of said inventions **does impose an undue burden** of searching on the examiner.

In conclusion restriction with respect to Groups 1(b)-1 (c) is maintained and is hereby made **final**.

DETAILED ACTION

Claims 1-2 and 4-8, drawn only to a method of screening for modulators of KIF18A polypeptide utilizing small non-nucleic acid organic molecules, are under examination on the merits.

Claims 3, 9-41 are withdrawn as drawn to non-elected invention.

Claim Objections

Claims 1-2 and 4-8 are objected to because of the following informalities: claim 1 still recites non-elected subject matter namely, KLP67A. Applicant is advised to delete non-elected subject matter from said claims (claims 2, 4-8 are merely objected to for depending from claim 1, under objection. Claim 4 is additionally objected for Reciting non-elected subject matter, namely siRNA, ribozomes etc. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "GenBank Accession Number AL136819" is unclear. This is because GenBank database frequently updates its contents and

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renumbers accession numbers. Therefore, said accession number cannot be relied upon for identification of KIF18A polypeptide sequence on a permanent basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is directed to a method of use of a **genus** of KIF18A polypeptides which have been merely defined by function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that "in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. accordingly, such a

formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, Applicant is claiming a **genus** of KIF18A polypeptides by what it does rather than what it structurally is. All applicant provides is a **single species**, namely SEQ ID NO:2 which is insufficient to characterize all members of the genus and this type of characterization fails to meet written description requirements of 112 first paragraph. Claims 2, 4-8 are merely rejected for depending from a rejected base claim.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening modulators of KIF18A comprising detecting localization of KIF18A to a region of a dividing cell other than the distal ends of astral microtubules in the presence of the test compound, does not reasonably provide enablement for a method of identifying for modulators of KIF18A

comprising detecting an altered localization of KIF18A polypeptide in the test cell as compared to KIF18A polypeptide in the control cell.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which regions beyond nucleus of dividing cells and specifically away from the distal ends of astral microtubules can modulate KIF18A polypeptide localize to. No examples of such regions are provided either. Current state of prior art indicates that "altered localization" within a cell, includes moving from nucleus to the cytoplasm, vice versa, moving to membrane or vice versa, moving to specific organelles such as ribosome etc. and the pattern of localization changes if the cell is dividing or not.

Therefore due to lack of sufficient guidance and examples provided in the specification and due to unpredictability of prior art as to which "altered localization" regions within the dividing and non-dividing cells are likely targets of modulated KIF18A polypeptides one of skill in the art has to go through the burden of undue experimentation in order to screen for those "altered localization" regions that are supported by the specification and as such the claims go beyond the scope of the disclosure. Claims 3-4 and 6-8 are merely rejected for depending from rejected base claim.

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Note:

The following art may be of relevance to this invention:

WO 01/12659 issued 22 feb 2001

WO 02/12268 issued 14 Feb 2002.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Maryam Monshipouri Ph.D.
Primary Examiner
